CONTINUING REVIEW APPLICATION

SUBMISSION INSTRUCTIONS

Submit the Continuing Review Questionnaire Form and any other supporting documentation to the IRB office electronically (esc-irb@email.laccd.edu). No handwritten forms will be accepted.

LACCD IRB

770 Wilshire Boulevard

Los Angeles, CA 90017

esc-irb@email.laccd.edu

FOR LACCD IRB OFFICE USE ONLY

APPLICATION REVIEW

This application has been reviewed by the LACCD IRB as:

[ ]  Approved

[ ]  Approved Subject to Restrictions

[ ]  Refer to Full Committee Review

Comments:

Committee Co-Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CONTINUING REVIEW QUESTIONNAIRE

PROTOCOL INFORMATION

**Date Submitted:** Click here to enter a date.

**IRB Protocol Identification Number:** XXXX - XX - XXX

**Title of Study:** Click here to enter title.

**Campus:** Choose LACCD Campus:

**Principal Investigator (PI):** Click here to enter text.

**Federal Regulations mandate** that all human subject protocols receive continuing review and approval **not less than once per year**. In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a substantive and meaningful review. Therefore, in order for the Los Angeles Community College District IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/ documents are required:

[ ]  Completed Continuing Review Questionnaire

[ ]  Copies of all informed consent documents

[ ]  Survey and/or questionnaires currently being used

1. **Briefly summarize the study objectives and procedures?**

Click here to enter text.

1. **Dates covered by this progress report?**

[ ]  Previous 12 months

[ ]  Other periods. Please Describe: Click here to enter text.

1. **Project Summary**
2. ***Leadership.* Have there been any changes in leadership, responsibility, or major personnel?**

 [ ]  Yes [ ]  No

 **If Yes, then fully describe:**

 Click here to enter text.

1. ***Objectives.* Have there been any changes?**

 [ ]  Yes [ ]  No

 **If Yes, then fully describe:**

 Click here to enter text.

1. ***Procedures.* Have there been any changes?**

 [ ]  Yes [ ]  No

 **If Yes, then fully describe:**

 Click here to enter text.

1. ***Informed Consent Documents.* Have there been any changes?**

 [ ]  Yes [ ]  No

 **If Yes, then fully describe:**

 Click here to enter text.

1. ***Research Subjects.* List each group, cohort, etc., including control groups, on separate lines *(If Applicable)*. If there is only one group, the description would be “All.”**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **NUMBER OF SUBJECTS**(at all sites) | **AGE RANGE OF SUBJECTS**(at all sites) | **GENDER**(of subjects to dates) |
| Group | ThisPeriod | Next Period (Anticipated) | ThisPeriod | Next Period(Anticipated) | %Female | %Male |
| Click here to enter text. | XXXXX | XXXXX | Age Range | Age Range | XX | XX |
| Click here to enter text. | XXXXX | XXXXX | Age Range | Age Range | XX | XX |
| Click here to enter text. | XXXXX | XXXXX | Age Range | Age Range | XX | XX |
| Click here to enter text. | XXXXX | XXXXX | Age Range | Age Range | XX | XX |
| Click here to enter text. | XXXXX | XXXXX | Age Range | Age Range | XX | XX |

1. **Was the subject population representative of the population base from which subjects could be selected with respect to:**
	1. **Gender Representation?**  [ ]  Yes [ ]  No
	2. **Minority Representation?**  [ ]  Yes [ ]  No

**If No, please explain:**

 Click here to enter text.

1. **Have any subjects withdrawn from the study since it has begun?**

[ ]  Yes [ ]  No

**If Yes, please explain:**

Click here to enter text.

1. **Are you aware of any breach in confidentiality? (e.g., unauthorized access to records)**

[ ]  Yes [ ]  No

**If Yes, please explain:**

Click here to enter text.

1. ***Unexpected Problems.* Have there been any unexpected problems?**

[ ]  Yes [ ]  No [ ]  Not Applicable

**If Yes**, please summarize these unexpected problems, the number of occurrences, and indicate if they required consent document changes, particularly in the “risks” section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits. If available, attach copies of data safety monitoring reports.

Click here to enter text.

1. ***Proposed Revisions/Amendments/Modifications.* Are there revisions/amendments to the protocol, consent form(s), questionnaires, etc. that are included with this renewal?**

[ ]  Yes [ ]  No

**If Yes,** please provide a brief description below and highlight the changes on the documents to be reviewed.

Click here to enter text.

1. **Will the revisions/amendments change the scope or research objectives of the protocol?** The following are examples of actions considered to change the scope or research objectives: a change in the specific aims approved at the time of award (funding); a change from the previously approved use of human subjects, or; shifting the emphasis of the research from one disease to another.

[ ]  Yes [ ]  No [ ]  Not Applicable

**If Yes,** please provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

Click here to enter text.

1. **Will the revisions/amendments change risks to subjects?**

[ ]  Yes [ ]  No [ ]  Not Applicable

**If Yes,** please provide sufficient information/documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

Click here to enter text.

1. ***Publications, Presentations, & Reports.* Provide a listing of all publications, presentations, and reports that have resulted from this work since the last review. If none, so state.**

Click here to enter text.

PRINCIPAL INVESTIGATOR CERTIFICATION

As a **Principal Investigator**, I acknowledge that I am responsible for reporting any emergent problems; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the IRB Co-Chairpersons, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB’s understanding and recommendations, that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

**Signature of PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Faculty Advisor:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

*(if student)*